

## Message Text

UNCLASSIFIED

PAGE 01 TOKYO 15412 260242Z

64

ACTION HEW-06

INFO OCT-01 EA-10 ISO-00 OES-05 RSC-01 /023 W

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R 260211Z NOV 74

FM AMEMBASSY TOKYO

TO SECSTATE WASHDC 6299

UNCLAS TOKYO 15412

E.O. 11652: /A

TAGS: ETRD, EIND, TBIO, JA

SUBJECT: RECALL OF MEDICAL DEVICE-CARDIAC PACEMAKER

REF: STATE 248391

1. DR. MACHII OF MITSUI MEMORIAL HOSPITAL HAS CONFIRMED THAT CORDIS CARDIAC PACEMAKER OMNI-STANICOR MODEL 162C, SERIAL NO. 481 WITH DELTA 316B, SERIAL NO. 5 WAS IMPLANTED ON JUNE 28, 1973 AND WAS EXPLANTED JAN. 1974. UNIT WAS REPLACED BY CORDIS OMNI-STANICOR MODEL 162C, SERIAL NO. 2764.

2. YUFU ITONAGA CO., LTD., JAPANESE IMPORT AGENT FOR CORDIS, HAS INDICATED THAT IT HAS IMPORTED ABOUT 500 CORDIS PACEMAKERS TO DATE. CORDIS HAS NOTIFIED YUFU ITONAGA THAT IT IS RECALLING TWO OF PACEMAKER UNITS IMPORTED INTO JAPAN: OMNI-STANICOR MODEL 162C, SERIES NO. 4620 AND 1117. ACCORDING TO YUFU ITONAGA, UNIT NO. 4620 HAS NOT BEEN USED AND NO. 1117 HAD ALREADY BEEN EXPLANTED FROM PATIENT BEFORE RECALL ANNOUNCEMENT HAD BEEN MADE. CORDIS DID NOT INFORM YUFU ITONAGA CO. THAT UNIT USED BY DR. MACHII (MODEL 162C, SERIAL NO. 481, MENTIONED PARA. 1) WAS BEING RECALLED.

3. EMBASSY HAS PROVIDED DR. MACHII WITH COPY OF REFTEL SINCE HE WAS NOT PREVIOUSLY AWARE OF RECALL. YUFU ITONAGA IS ALSO PASSING ON INFORMATION IT RECEIVED FROM CORDIS.  
HODGSON

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 26 NOV 1974  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
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**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** n/a  
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**Film Number:** D740342-0354  
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**Original Handling Restrictions:** n/a  
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**Previous Handling Restrictions:** n/a  
**Reference:** STATE 248391  
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**Review Date:** 06 NOV 2002  
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**Review Transfer Date:**  
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**Secure:** OPEN  
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**Subject:** RECALL OF MEDICAL DEVICE-CARDIAC PACEMAKER  
**TAGS:** ETRD, EIND, TBIO, JA  
**To:** STATE  
**Type:** TE  
**Markings:** Declassified/Released US Department of State EO Systematic Review 30 JUN 2005